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510(k) Summary
Abbott AxSYM® Digitoxin

Summary of Safety and Effectiveness Information Supporting a
Substantial Equivalent Determination

The Abbott AxSYM Digitoxin assay is substantially equivalence to the TDx/TDxFLx Digitoxin assay. Both assays are automated fluorescence polarization immunoassays (FPIA). The intended use of both assays is for the quantitative determination of digitoxin in human serum or plasma (sodium heparin and potassium oxalate). Both assays are calibrated with Abbott calibrators. Abbott controls are used for verification of accuracy and precision of the AxSYM system when used for the quantitative determination of digitoxin in human serum or plasma. Correlation studies indicated the following results:

Slope: 0.96
Y-intercept: 0.58
Correlation Coefficient: 0.97
Std. Error of the Y estimate: 1.87
Number: 517

The AxSYM Digitoxin standard calibrators and controls are to be used with the AxSYM Digitoxin reagents. The calibrators and controls are prepared gravimetrically using purified material obtained from commercial sources. The calibrators and controls are verified using protocols involving multiple instrument testing. AxSYM Digitoxin reagent, calibrator and control expiration dates are based on real time stability testing.

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